

## Clinical Edit Criteria Proposal

Drug/Drug Class: Revatio® Clinical Edit

Date: September 28, 2005

Prepared for:

Prepared by: Missouri Medicaid

☒ **New Criteria**

☐ **Revision of Existing Criteria**

### Executive Summary

**Purpose:** Ensure appropriate utilization and control of Revatio® (sildenafil tablets).

**Why was this  
Issue  
Selected:**

Revatio® is a branded drug product containing sildenafil citrate, the same active ingredient in Viagra. The product is indicated for the treatment of pulmonary arterial hypertension (PAH). Consistent with sildenafil's known effects, Revatio® has been shown to potentiate the hypotensive effects of nitrates, and therefore concomitant administration is contraindicated. Co-administration of ritonavir, ketoconazole, or itraconazole, and Revatio substantially increases serum concentration of sildenafil, therefore is not recommended. This product is available in a 20mg tablet formulation.

Program-specific information:	Drug	Dosage Form	Cost per Dosage Form
	• Revatio®	20mg tab	\$11.1642AWP

**Setting & Population:** All patients.

**Type of Criteria:**

☐ Increased risk of ADE

☒ Appropriate Indications

☐ Non-Preferred Agent

☐

Data Sources: ☐ Only administrative  
databases

☒ Databases + Prescriber-  
supplied

## Setting & Population

- Drug for review: Revatio® (sildenafil tablets)
- Age range: All ages
- Gender: Male and female

## Approval Criteria

- Diagnosis of Pulmonary Arterial Hypertension (PAH)
- Patient's profile free of any form of nitrates in the last 30 days.
- Patient's profile free of retonavir (Norvir®) in the last 30 days.
- Product dosing 20mg three times daily.

## Denial Criteria

- Failure to meet approval criteria.

## References

1. Pfizer Labs, Division of Pfizer Inc., "Revatio Product Submission", New York, NY 10017. July 2005.
2. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2005.
3. USPDI, Micromedex, 2005.

